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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,781	04/21/2004	Donna E. Fennell	RU-0224	5233

7590 09/09/2009

Jane Massey Licata
Licata & Tyrrell P.C.
66 E. Main Street
Marlton, NJ 08053

EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
09/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Note:

The proposed amendment raises new issues that would require further consideration and/or search with respect to the extensive amendments to claims 1 and 5 to inlude a mixed culture comprising strain *Dehalococcoides ethenogenes* 195 and "another *Dehalococcoides ethenogenes* strain" and the proviso "wherein said *Dehalococcoides ethenogenes* strain 195 is present in the culture at a concentration percentage of from 30 to 80 percent of the total culture", including issues of new matter. The context of the cited pages cannot be readily assessed.

It should be kept in mind that applicant cannot, as a matter of right, amend any finally rejected claims, add new claims after a final rejection (see **37 CFR 1.116**) or reinstate previously canceled claims.

Except where an amendment merely cancels claims, adopts examiner suggestions, removes issues for appeal, or in some other way requires only a cursory review by the examiner, compliance with the requirement of a showing under **37 CFR 1.116(b)(3)** is expected in all amendments after final rejection, i.e., " An amendment touching the merits of the application or patent under reexamination may be admitted upon a showing of good and sufficient reasons why the amendment is necessary and was not earlier presented."

Response to Arguments

Applicant's arguments as they pertain to the claims on record have been fully considered but they are not deemed to be persuasive.

Applicant's arguments regarding the differences between *Dehalococcoides* CBDB1 and *Dehalococcoides ethenogenes* are duly noted. However, applicant fails to consider that the Adrian *et al.* reference suggests that *Dehalococcoides ethenogenes* 195 and *Dehalococcoides* CBDB1 have similar dechlorinating capabilities as suggested by the finding that in both of these strains reductive dehalogenation of chlorinated compounds is the only energy conserving process found. Moreover that the strains are closely related as they belong to the same genus is shown in Figure 2. Therefore, even though the strains do not appear to be identical one of ordinary skill in the art would have recognized their similarity and would thus have reasonably expected at the time the claimed invention was made that *Dehalococcoides ethenogenes* 195

would be suitable to perform similar dehalogenation reactions on aromatic halogenated compounds as strain *Dehalococcoides* CBDB1 See, also Figure 3 in Bunge *et al.*.

It is emphasized that this obviousness rejection is based on the close relatedness between the reference and claimed strain, which both belong to the same genus *Dehalococcoides*. Applicant cites Ward for broad teachings regarding metabolic differences between organisms as well as the lack of absolute predictability of 16S rRNA sequences regarding metabolic capabilities between strains. These broad teachings are not relevant to the invention as claimed with any specificity. Applicant also cites the abstract of Cupples (2008) as showing that strains with the same 16S RNA gene sequence can have different dehalogenating abilities. Whether this is applicable to the two strains of interest is not particularly shown. In addition, this information was not available to one of ordinary skill in the art at the time the claimed invention was made.

Even though the strains *Dehalococcoides ethenogenes* 195 and *Dehalococcoides* CBDB1 are not the same and have certain differences in metabolic requirements, they belong to the same genus *Dehalococcoides* and would have been reasonably expected to successfully perform a process of removing at least one halogen group from a halogenated aromatic compound, as in claim 1, at the time the claimed invention was made, due to the teachings of the references. Applicant has not demonstrated differences or unexpected results in the claimed process between the claimed strain and the reference strain, which both appear to belong to the genus *Dehalococcoides* and which are both known to successfully decompose halogen containing compounds.

That the two strains of interest are closely related cannot be denied, even if the similarity between the 16S rRNA is not absolutely predictive of the functional genes an organism may possess. Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) (Claims directed to a method for the commercial scale production of polyesters in the presence of a solvent at superatmospheric pressure were rejected as obvious over a reference which taught the claimed method at atmospheric pressure in view of a reference which taught the claimed process except for the presence of a solvent. The court reversed, finding there was no reasonable expectation that a process combining the prior art steps could be successfully scaled

up in view of unchallenged evidence showing that the prior art processes individually could not be commercially scaled up successfully.). See also *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1207-08, 18 USPQ2d 1016, 1022-23 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991) (In the context of a biotechnology case, testimony supported the conclusion that the references did not show that there was a reasonable expectation of success.); *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (The court held the claimed method would have been obvious over the prior art relied upon because one reference contained a detailed enabling methodology, a suggestion to modify the prior art to produce the claimed invention, and evidence suggesting the modification would be successful.). See, MPEP 2143.02.

In addition, it is noted that claims 5 and 7 do not require the use of strain *Dehalococcoides ethenogenes* 195. Therefore the arguments do not pertain to these claims.

The arguments directed to claims that are not entered are not considered.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
Art Unit 1651